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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,354

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Antonio Bernad Miana

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EXAMINER

SAJJADI, FEREDYDOUN GHOTB

ART UNIT

PAPER NUMBER

1633

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,354	<b>Applicant(s)</b> BERNAD MIANA ET AL.	
	<b>Examiner</b> FEREYDOUN G. SAJJADI	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-30 are pending in the Application.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15 and 20-23, drawn to an isolated population of adult multipotent stem cells from dedifferentiated chondrocytes of mammal articular cartilage; and a pharmaceutical composition comprising the same.

Group II, claim(s) 16-18, drawn to an isolated transgenic cell population derived from adult multipotent stem cells from dedifferentiated chondrocytes of mammal articular cartilage, characterized by having a modified genome.

Group III, claim(s) 19, drawn to a method of using an isolated population of adult multipotent stem cells from dedifferentiated chondrocytes of mammal articular cartilage, to prepare a pharmaceutical composition.

Group IV, claim(s) 24 and 25, drawn to an *in vitro* method for evaluation of cellular response of an isolated population of adult multipotent stem cells from dedifferentiated chondrocytes of mammal articular cartilage, to biological or pharmaceutical agents.

Group V, claim(s) 26-30, drawn to an *in vivo* method for evaluation of cellular response of an isolated population of adult multipotent stem cells from dedifferentiated chondrocytes of mammal articular cartilage, to biological or pharmaceutical agents comprising implanting said cells in an experimental animal model.

Please note that PCT Rule 13.2, no longer specifies the combinations of categories of invention which are considered to have unity of invention. The categories of invention in former PCT Rule 13.2 have been replaced with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term “special technical features” is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

2. Groups II claims encompass a plurality of distinct inventions exemplified by structurally distinct transgenic cells and their various modifications, that comprise distinct compositions. These are exemplified by genome modifications by insertion, replacement or inactivation. Because the resulting transgenic cells are structurally and likely functionally distinct, having characteristics not commonly shared, they lack unity of invention. Applicant is required to choose a single, specific type of transgenic cell modified by either insertion, replacement or inactivation of at least one portion of the cellular genome, should the inventions of Groups II be elected for examination. This is not a species restriction requirement.

37 CFR 1.475 (e) states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.”

In view of 37 CFR 1.475 (e), Group II is considered a plurality of the inventions listed in claim 16.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature,

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which is shared by Groups I-V, is a multipotent cell from dedifferentiated mammalian chondrocytes.

Groups I-V do not share a special technical feature over the art because the inventions lack an inventive step under PCT Article 33(3) as being obvious over Barbero et al. (Arthritis & Rheumatism 48(5):1315-1325; 2003), who describe dedifferentiated adult human chondrocytes that can differentiate toward diverse mesenchymal lineages, thus displaying characteristics of mesenchymal progenitor cells (Abstract).

The claims in Groups I-V are drawn to a distinct products (i.e. multipotent and transgenic stem cells), and a distinct methods employing distinct steps (i.e. to prepare a pharmaceutical or to evaluate cellular responses *in vitro* and *in vivo*), requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-V do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

The inventions of Groups I and III-V constitute products and related process. MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specifically named single species of positive cell surface antigen such as CD9, CD13, CD29, CD44, CD49a, CD49b, CD49c, CD49e, CD54, CD55, CD58, CD59, CD90, CD95,

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CD105, CD106, CD166, HLA-1 and beta2-microglobulin; and a specifically named single species of negative cell surface antigen, such as CD10, CD11 b, CD14, CD15, CD16, CD18, CD19, CD28, CD31, CD34, CD36, CD38, CD45, CD49d, CD50, CD51, CD56, CD61, CD62E, CD62L, CD62P, CD71, CD102, CD104, CD117, CD133, and HLA-II, as recited in claims 1 and 2.

A specifically named single species of specialized cell, such as chondrocytes, osteocyte, adipocyte, myocyte, cardiomyocyte, neuron, astrocytes, oligodendrocyte, epithelial cell, hepatocytes and pancreatic cell, as recited in generic claim 4 and dependent claims 5-15.

A specifically named single species of disease tissue, such as cartilage, bone, muscle, heart, central and peripheral nervous system, skin, liver and pancreas, as recited in claims 19.

A specifically named single species of pharmaceutical component, such as growth factors, cytokines, chemokines, extracellular matrix proteins, drugs and synthetic polymers, as recited in claim 21.

A specifically named single species of biocompatible synthetic structure, such as a microparticle, microsphere, nanoparticle and nanosphere type, as recited in claims 23 and 29.

A specifically named single species of pharmaceutical agent, such as peptides, antibodies, cytokines, chemokines, growth factors, hormones, viral particles, antibiotics, inhibitor compounds, chemotherapy agents, cytotoxic agents, mutagens, food additives, pharmaceutical compositions and vaccines, as recited in claims 25 and 30.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 2, 5-15, 19, 21, 23, 25, 29, 30 and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 1-30

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical features for (CD9, CD13, CD29, CD44, CD49a, CD49b, CD49c, CD49e, CD54, CD55, CD58, CD59, CD90, CD95, CD105, CD106, CD166, HLA-1 and beta2-microglobulin; and a specifically named single species of negative cell surface antigen, such as CD10, CD11 b, CD14, CD15, CD16, CD18, CD19, CD28, CD31, CD34, CD36, CD38, CD45, CD49d, CD50, CD51, CD56, CD61, CD62E, CD62L, CD62P, CD71, CD102, CD104, CD117, CD133, and HLA-II, chondrocytes, osteocyte, adipocyte, myocyte, cardiomyocyte, neuron, astrocytes, oligodendrocyte, epithelial cell, hepatocytes and pancreatic cell, cartilage, bone, muscle, heart, central and peripheral nervous system, skin, liver and pancreas, growth factors, cytokines, chemokines, extracellular matrix proteins, drugs and synthetic polymers, microparticle, microsphere, nanoparticle and nanosphere type, peptides, antibodies, cytokines, chemokines, growth factors, hormones, viral particles, antibiotics, inhibitor compounds, chemotherapy agents, cytotoxic agents, mutagens, food additives, pharmaceutical compositions and vaccines) linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species is structurally and likely functionally distinct, capable of separate utility, and does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double



patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

Fereydoun G. Sajjadi, Ph.D.  
Examiner, Art Unit 1633